

Data Evaluation Report on the phototransformation of fenamidone on soil

PMRA Submission Number {.....}

EPA MRID Number 45385901

Data Requirement: PMRA Data Code:
EPA DP Barcode: D275213
OECD Data Point:
EPA Guideline: 161-3

Test material:

Common name: Fenamidone

Chemical name

IUPAC: (+)-(4S)-4-Methyl-2-methylthio-4-phenyl-(1H)-1-phenylamino-2-imidazolin-5-one.

CAS name: 4H-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-, (S)-.

CAS No: 161326-34-7.

Synonyms: Reason 500 SC Fungicide.

Methyl-2-methylthio-5-phenyl-3-phenylamino-3,5-dihydro-4H-imidazol-4-one.

(S)-1-Anilino-4-methyl-2-methylthio-4-phenylimidazolin-5-one.

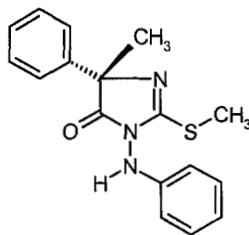
(S)-5-Methyl-2-methylthio-5-phenyl-3-phenylamino-3,5-dihydroimidazol-4-one.

Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-, (5S)-.

(5S)-3,5-Dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-4H-imidazol-4-one.

RPA407213.

SMILES string:

Chemical Structure:

Primary Reviewer: Lynne Binari
Dynamac Corporation

QC Reviewer: Kathleen Ferguson
Dynamac Corporation

Secondary Reviewer: Silvia Termes
EPA

Signature:**Date:****Signature:****Date:****Signature:****Date:**

*Signed by
Dynamac's
reviewer
on 2/14/02*

[Signature]

26 August, 2002



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RPA407213.

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Date: 2/14/02

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EPA

Signature:
Date:

Company Code: [for PMRA]

Active Code: [for PMRA]

Use Site Category: [for PMRA]

EPA PC Code: 046679

CITATION: Burr, C.M. 1999. [N-phenyl-U-¹⁴C]-RPA407213 photodegradation in soil.

Unpublished study performed by Rhône-Poulenc Agricultural Ltd., Essex, United Kingdom, and sponsored by Aventis CropScience, Research Triangle Park, NC (pp. 1, 2). Laboratory Study Number 16286. Document No. 202094. The study was completed July 8, 1999 (p. 1); a study initiation date was not reported, but the experimental start date was November 4, 1998 (p. 27).

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Regulatory Conclusions: This study conducted with [N-phenyl-U-¹⁴C]-labeled fenamidone was deemed acceptable (45385901). fenamidone (45385832). Together with the acceptable study conducted with [C-phenyl-U-¹⁴C]-labeled fenamidone (45385832), it may be used to fully satisfy Subdivision N Guideline §161-3.

EXECUTIVE SUMMARY

The phototransformation of [N-phenyl-U-¹⁴C]-labeled (+)-(4*S*)-4-methyl-2-methylthio-4-phenyl-(1*H*)-1-phenylamino-2-imidazolin-5-one (fenamidone, RPA407213) was studied on sandy loam soil (pH in water 4.8, organic carbon 1.2%) from Wisconsin at a nominal concentration of 19.9 mg a.i./kg soil for 30 days at 20 ± 1°C and 75% of 0.33 bar moisture. This experiment was conducted in accordance with USEPA Subdivision N Guideline §161-3 and in compliance with OECD Principles of GLP as specified by U.K. GLP Regulations (1997, No. 654 Health & Safety). The treated samples were irradiated under a 12.7-hour daylight/11.3-hour darkness photoperiod using a UV-filtered xenon arc lamp (290-800 nm, average light intensity 325.2 W/m²); it was calculated that 12.7 hours of xenon lamp irradiation was equivalent to 1 day of clear midday summer sunlight at 50°N latitude. Each irradiated test system consisted of treated soil contained in an open quartz dish (2.6-cm dia.) incubated within a double-walled glass vessel (4-cm dia.) sealed with a quartz disc and equipped with inlet/out ports to allow for collection of CO₂ and organic volatiles at each sampling interval. Treated dark control soils were similarly incubated in a temperature-controlled room. Duplicate irradiated and dark control soils were taken after 0, 2, 5, 9, 15, 21 and 30 days. All soil samples were sequentially extracted with acetonitrile and acetonitrile:water (1:1, v:v), samples after day 0 were also Soxhlet-extracted with acetonitrile:water (1:1, v:v), and 5- to 30-day samples were further Soxhlet-extracted with deionized water. Soil extracts were analysed by reverse-phase HPLC and normal-phase one-dimensional TLC; identifications of fenamidone and transformation products were based on comparative HPLC retention times and TLC R_f values with unlabeled reference standards. Identifications of [¹⁴C]compounds were confirmed using LC/MS with electrospray ionization (ESP) in positive ion mode.

During the 30-day study, mean (n = 2, except n = 1 for irradiated days 21 and 30 and dark control day 15) material balances decreased from an initial 99.70 ± 0.72% of the applied radioactivity to 90.22% at 30 days in irradiated soil to 87.84-92.69% at 21-30 days in dark control soil. Irradiation did not significantly affect the rate of transformation of [C-phenyl-¹⁴C]fenamidone or the transformation products formed when incubated on sandy loam soil at 20 ± 1°C and 75% of 0.33 bar moisture. [¹⁴C]Fenamidone decreased from 99.36 ± 0.74% of the applied at day 0 to 56.84 ± 3.76% at 9 days and 31.08% at 30 days in irradiated soil extracts and to 55.49 ± 9.19% at 9 days and 13.83-20.31% at 21-30 days in dark control soil extracts. The slower rate of transformation of [¹⁴C]fenamidone on the irradiated soil may have been the result of difficulty in maintaining the soil moisture content at a constant level. No major transformation products were detected in irradiated and dark control soil extracts. Minor transformation products identified in irradiated and dark control soil extracts were RPA405862 (5-methyl-5-phenyl-3-phenylaminoimidazolidine-2,4-dione) detected at maximums of 7.60% (21 days) and 4.22% (9 days), respectively; RPA410914 (5-methyl-

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2-methylthio-3-(2-nitrophenylamino)-5-phenyl-3,5-dihydroimidazol-4-one) at 6.96% (15 days) and 8.96% (30 days), respectively; and RPA406012 (5-methyl-2-methylthio-3-(4-nitrophenylamino)-5-phenyl-3,5-dihydroimidazol-4-one) at 4.31% (15 days) and 3.03% (15 days), respectively. Up to twenty-nine unidentified [^{14}C]compounds were each detected at $\leq 7.04\%$ of the applied. Volatilized $^{14}\text{CO}_2$ totaled 3.56% for irradiated soils and 4.87% of the applied for dark control soils; organic [^{14}C]volatiles were $\leq 0.01\%$ of the applied.

Extractable [^{14}C]residues decreased from $99.60 \pm 0.73\%$ of the applied at day 0 to 77.03% at 30 days in irradiated soil and 69.90-76.00% in dark control soil; over the same intervals nonextractable [^{14}C]residues increased from $0.10 \pm 0.01\%$ of the applied to 9.63% in irradiated soil and 11.93-15.57% in dark control soil. For nonextractable [^{14}C]residues in 15- and 30-day dark control and 21- and 30-day irradiated soil samples, 1.84-2.55% of the applied was associated with the fulvic acid, 3.20-5.26% with humic acid and 3.03-5.42% with humins.

Half-life values of [N-phenyl- ^{14}C]fenamidone, based on first-order kinetics and linear regression, were 11.0 days ($r^2 = 0.0.879$) on dark control soil and 18.7 days ($r^2 = 0.0.927$) on irradiated soil based on the continuous irradiation conditions used in this study. Registrant-calculated nonlinear (two compartment decay) DT_{50} values were 7.90 and 12.63 days on dark control and irradiated soil, respectively; the DT_{90} value for the irradiated sample was 40.77 days.

Since the rate of degradation was faster in the dark control than the irradiated samples, the **phototransformation half-life** could not be determined.

A transformation pathway for the degradation of [N-phenyl- ^{14}C]fenamidone on soil was not proposed by the registrant because no unique transformation products resulted from the irradiation and no significant transformation products ($>10\%$ of the applied radioactivity) were produced. The transformation pathway determined from the degradation of [C-phenyl- ^{14}C]fenamidone on sandy loam soil (MRID 45385832) was referenced. The transformation of [C-phenyl- ^{14}C]fenamidone on soil (again no unique transformation products resulted from irradiation) proposed by the registrant included fenamidone degrading to RPA408056 (5-methyl-2-methylthio-5-phenyl-3,5-dihydroimidazol-4-one) via loss of the aniline ring, with further degradation to RPA717879 (5-methyl-5-phenylimidazolidine-2,4-dione) via hydrolysis to release the methylthio group and eventual mineralization to CO_2 .

Results Synopsis:

Soil type:	Sandy loam.
Source of irradiation:	Artificial xenon arc lamp.
Half-life value for dark:	11.0 days ($r^2 = 0.879$).
Half-life value for irradiated:	18.7 days ($r^2 = 0.927$).

Major transformation products: None.

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Minor transformation products: 5-methyl-5-phenyl-3-phenylaminoimidazolidine-2,4-dione (RPA405862).
5-Methyl-2-methylthio-3-(2-nitrophenylamino)-5-phenyl-3,5-dihydroimidazol-4-one (RPA410914).
5-Methyl-2-methylthio-3-(4-nitrophenylamino)-5-phenyl-3,5-dihydroimidazol-4-one (RPA406012).
Twenty-nine unidentified [¹⁴C]compounds.
CO₂.

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: This study was conducted in accordance with USEPA Subdivision N Guideline §161-3 and EU Commission Directive 95/36/EC of July 1995 amending Council Directive 91/414/EEC, Section 7.1.1.1.2 (p. 12). No significant deviations were noted.

COMPLIANCE: This study was conducted in compliance with OECD Principles of GLP as specified by U.K. GLP Regulations (1997, No. 654 Health & Safety; p. 3). Signed and dated GLP, Data Confidentiality, study Authentication, study Certification and Quality Assurance statements were provided (pp. 2-5, 27, 28).

A. MATERIALS:

1. Test Material: [N-Phenyl-U-¹⁴C]RPA407213

Chemical Structure:

Description: Not provided..

Purity:

[N-Phenyl-U-¹⁴C]-labeled: Radiochemical purity: ≥99.0% (p. 13, Appendix 1, pp. 78-80).
Batch No. PCH1502 (p. 12, Appendix 1, p. 78).
Optical purity: 100% (Appendix 1, p. 81).
Initial specific activity: 1,370 MBq/mM (37 mCi/mM).
Final specific activity following dilution with unlabeled fenamidone: 19 mCi/mM (703 MBq/mM, 2.25 MBq/mg; p. 13, Appendix 1, p. 83).

Unlabeled: Purity 99.5% (p. 13).
Batch No. MCD1905.

Storage conditions of test chemical:

Not specified.

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Table 1: Physico-chemical properties of fenamidone.

Parameter	Details	Comments
Solubility:	7.8 mg/L in water at 20°C. 86.1 g/L in acetonitrile at 20°C.	Data obtained from p. 10, MRID 45385831.
Vapor pressure/volatility:	Not reported.	
UV absorption:	<300 nm	In methanol:pH 7 buffer solution (90:10, v:v; p. 57, MRID 45385830).
pK _a :	Not reported.	
K _{ow}	Not reported.	
Stability at room temperature:	Not reported.	

2. Soil Characteristics:

Table 2: Description of soil collection and storage.

Description	Nisse
Geographic location:	Hill Top Farm, Iola, Wisconsin, U.S.A.
Collection date:	July 24, 1998.
Storage conditions:	4°C.
Soil preparation:	Moistened (moisture content not specified), aerated, then 2 mm sieved.

Data obtained from p. 13 in the study report.

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Table 3: Properties of the soils.

Property	Nisse
Soil texture:	Sandy loam.
% sand (50-2000 μm):	66.99.
% silt (2-50 μm):	26.66.
% clay (<2 μm):	6.35.
pH:	4.8 in water. 3.8 in 1 M KCl. 4.2 in 0.01 M CaCl_2 .
Organic carbon (%):	1.2.
Organic matter (%; calculated):	2.1.
CEC (meq/100 g):	17.0.
Moisture at 1/3 atm (%):	12.8.
Bulk density (g/cm^3):	Not provided.
Microbial biomass ($\mu\text{g C/g soil}$):	105; fumigation-extraction method.
Soil Taxonomic classification:	Not provided.
Soil Mapping Unit (for EPA):	Not provided.

Data obtained from p. 30 in the study report.

3. Details of light source:

Table 3: Artificial light source.

Property	Details
Type of lamp used:	Xenon lamp, Heraeus Hanau Suntest.
Emission wavelength spectrum:	290-800 nm.
Light intensity:	Averaged $325.2 \text{ W}/\text{m}^2$, measured with a Heraeus Radialux global sensor (wavelength range not specified) at same distance as soil surface.
Filters used:	UV filter eliminated radiation <290 nm.
Relationship to natural sunlight:	12.7 hours of xenon lamp irradiation was equal to 1 day of clear midday summer sunlight at 50°N latitude.

Data obtained from p. 14; Appendix 4, pp. 87-88 in the study report.

B. EXPERIMENTAL CONDITIONS:

1. Preliminary experiments: None.

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2. Experimental conditions:

Table 4: Experimental design.

Parameter		Details
Duration of the test:		30 days.
Condition of soil:	Air dried/fresh:	Fresh.
	Sterile/non-sterile:	Non-sterile.
Soil (g/replicate):		4 g dry wt.
Test concentration:	Nominal:	19.9 mg a.i./kg soil; 22.5 kg a.i./ha.
	Actual:	20.2-20.8 mg a.i./kg soil; 22.8-23.5 kg a.i./ha.
Dark controls used (Yes/No): Method to maintain darkness:		Yes. Samples were incubated in darkness in a temperature-controlled room.
Replications	Dark controls:	Duplicate.
	Irradiated:	Duplicate.
Identity and concentration of co-solvent:		Acetonitrile, 100%.
Test material application.	Volume of test solution used/treatment:	0.045 mL of 1.68 mg a.i./mL test solution.
	Application method:	Applied drop-wise to soil surface. Soil was not mixed following application.
	Is the co-solvent evaporated?	No.
Test apparatus (Type/material/ volume):		An open quartz dish (2.6 cm diameter), containing treated soil (depth ca. 1 cm), was incubated within a double-walled, glass vessel (4 cm diameter, 13.1 cm height) equipped with inlet/outlet ports and sealed with a quartz disc.
Details of traps for CO ₂ and organic volatiles, if any:		Humidified, CO ₂ -free air was purged (flow rate not specified) through each vessel then sequentially through traps containing ethylene glycol (one trap) and 2 M KOH (two traps).
If no traps were used, is the system closed/open?		Volatiles traps were used.
Any indication of the test material adsorbing to the walls of the test apparatus?		Not indicated.

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Parameter			Details
Experimental conditions.	Temperature (°C):	Dark controls:	Temperature controlled room maintained at 20 ± 1°C.
		Irradiated:	Soil surface maintained at 20 ± 1°C via a water:ethylene glycol coolant circulated through the double-wall of each vessel with a flow-heater/cooler. The soil surface temperature was monitored with a temperature probe connected to the flow-heater/cooler.
	Moisture content: Moisture maintenance method:		75% of 0.33 bar. Samples weighed at each sampling interval and water added, as needed, equivalent to weight lost.
	Duration of light/darkness:		12.7-hour light/11.3-hour dark cycle.
	Distance from light source to soil surface:		29.5 cm.
Other details, if any:			None.

Data obtained from pp. 13-15; Figure 1, p. 43; Appendix 7, pp. 99-100 in the study report.

3. Supplementary experiments: None.

4. Sampling:

Table 5: Sampling details.

Parameters	Details
Sampling intervals for soil:	0, 2, 5, 9, 15, 21 and 30 days.
Sampling method:	Duplicate day 0 samples. Duplicate irradiated and dark control samples at all other intervals.
Method of collection of volatile compounds, if any:	Trapping solutions were collected and replaced at each sampling interval after day 0.
Sampling intervals/times for: Sterility check: Moisture content:	Sterile controls were not used. At each sampling interval.
Sample storage before analysis:	Extraction procedures initiated upon sample collection.
Other observations, if any:	None

Data obtained from p. 15; Table 2, p. 31 of the study report.

C. ANALYTICAL METHODS:

Extraction/clean up/concentration methods: Each soil sample was extracted with acetonitrile (25 mL x 2) followed by acetonitrile:water (1:1, v:v; 25 mL) using a wrist action shaker for 15 minutes

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per extraction (pp. 15, 16). All extracted soil samples, except day 0, were further Soxhlet-extracted with acetonitrile:water (1:1, v:v; volume not specified) for 20 hours, then 5- to 30-day extracted soils were lastly Soxhlet-extracted with deionized water (50 mL) for 20 hours with a final water extraction (15 mL x 2) using a wrist action shaker for 5 minutes per extraction (pp. 15, 17). All extracts were separated from the soil by centrifugation with like extracts combined. The acetonitrile and acetonitrile:water extracts were combined and analyzed directly (p. 18). Soxhlet acetonitrile:water extracts were concentrated by rotary evaporation (35°C) prior to analysis. Aliquots (0.25 mL) of the soil extracts were analyzed for total radioactivity by LSC (Appendix 7, pp. 101, 103, 104, 109, 110, 115, 116, 120, 121, 126, 127, 133, 134).

Nonextractable residue determination: Extracted soil samples plus respective cellulose thimbles (from Soxhlet extractions) were air-dried, homogenized using a Labtechnics LM1-P mill, then triplicate aliquots were analyzed for total radioactivity by LSC following combustion (p. 18). To characterize unextractable [¹⁴C]residues in the soil, selected previously extracted soil samples were further extracted first with 0.01 M calcium chloride followed by 0.5 M sodium hydroxide using a wrist action shaker for 24 hours per extraction (p. 18). The extract was separated from soil by centrifugation, acidified with 6 M hydrochloric acid to pH 1, and the resulting precipitate (humic acid) was removed by centrifugation. The remaining extract (fulvic acid) was analyzed by LSC. Quantitation methods for the humic acid precipitate and [¹⁴C]residues remaining in the extracted soil (humin) were not specified.

Volatile residue determination: Aliquots of each trapping solution were analyzed for total radioactivity by LSC (p. 18).

Total ¹⁴C measurement: Total ¹⁴C residues were determined by summing the concentration of residues measured in the soil extracts, extracted soil, and volatile trapping solutions.

Derivatization method, if used: A derivatization method was not employed.

Identification and quantification of parent compound: The combined acetonitrile/acetonitrile:water soil extracts and Soxhlet acetonitrile:water extracts were further analyzed by HPLC and TLC; the Soxhlet water extracts did not contain sufficient levels of [¹⁴C]residues (≤5.40% of the applied) at any sampling interval to allow further analysis (pp. 23- 24; Tables 3-4, pp. 32-33). Aliquots of the combined acetonitrile/acetonitrile:water extracts and Soxhlet acetonitrile:water extracts were analyzed by reverse-phase HPLC Method 1 under the following conditions: Hichrom Kromasil KR100-5C1 column (4.6 x 250 mm, particle size not specified), gradient mobile phase combining (A) water:acetonitrile (80:20, v:v), (B) water:acetonitrile (60:40, v:v) and (C) acetonitrile [percent A:B:C at 0 min. 100:0:0 (v:v), 5 min. 100:0:0, 10 min. 0:100:0, 35 min. 0:100:0, 40 min. 0:0:100, 50 min. 0:0:100, 55 min. 100:0:0, 65 min. 100:0:0], injection volume not specified, flow rate 1 mL/minute, UV (230 nm) and radioactivity detection (p. 19, 20, 47-50, 52, 53, 55, 56, 58, 59, 61, 62, 64, 65). Aliquots of the combined acetonitrile/acetonitrile:water soil extracts after day 0 were also analyzed by reverse-phase HPLC Method 2 under the following conditions: Hichrom Kromasil KR100-5C1 column (4.6

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x 100 mm, particle size not specified), gradient mobile phase combining (A) water:acetonitrile (60:40, v:v) and (B) acetonitrile [percent A:B at 0 min. 100:0 (v:v), 35 min. 0:100, 38 min. 100:0, 42 min. 100:0], and all other conditions as described for Method 1 (pp. 51, 54, 57, 60, 63, 66). Unlabeled reference standards (Table 16, pp. 41-42) were chromatographed with the extracts and identification of [^{14}C]fenamidone in the soil extracts was based on comparative retention times.

Selected soil extracts were also analyzed by normal-phase one-dimensional TLC conducted on silica gel plates developed with ethyl acetate:hexane (65:35, v:v; pp. 20, 21; Figures 35-36, pp. 73-74). Unlabeled reference compounds were co-chromatographed with the soil extracts. Following development, distribution of radioactivity was determined using an Ambis Radioanalytical Imaging System. Unlabeled reference compounds were detected under UV light (254 nm) and identifications of [^{14}C]fenamidone in the soil extracts were based on comparative R_f values.

Identification of parent fenamidone in selected soil extracts was confirmed by full scan LC/MS with positive ion electrospray ionization (ESP; p. 21; Figures 29-34, pp. 67-72). Comparison was made to unlabeled reference standard parent fenamidone (RPA407213). LC conditions were as described for Method 1 above with an injection volume of 0.05 mL and 20:1 split of flow rate on column effluent; ca. 0.95 mL/minute into UV/radioactivity detectors and ca. 0.05 mL/minute into ion source. MS conditions were as follows: VG Quattro I Triple Quadripole MS, source temperature 150°C, capillary voltage 4.00 kV, HV lens 0.50 kV, cone voltage 25 V, bath gas nitrogen 300 L/hour, nebuliser gas nitrogen 20 L/hour, multiplier 650 V, positive ion scan range 125-800 a.m.u. at 2 sec./scan cycle.

Identification and quantification of transformation products: Transformation products were isolated and quantified by HPLC, TLC, and MS as described for the parent compound and identified by comparison to reference standards (Table 16, pp. 41-42).

Detection limits (LOD, LOQ) for the parent compound: Limits of detection for LSC, HPLC and TLC analyses were not reported.

Detection limits (LOD, LOQ) for transformation products: Limits of detection for LSC, HPLC and TLC analyses were not reported.

II. RESULTS AND DISCUSSION

A. TEST CONDITIONS: Reportedly moisture, temperature and other environmental conditions for the irradiated samples were maintained throughout the study; however, no supporting records were provided. At 6-7 days posttreatment, the dark control samples were outside the $20 \pm 1^\circ\text{C}$ temperature range for <4 hours; actual temperature measurements were not provided (p. 22).

B. MATERIAL BALANCE: Mean ($n = 2$, except $n = 1$ for irradiated days 21 and 30 and dark control day 15) total recoveries of radiolabeled material decreased from an initial $99.70 \pm 0.72\%$

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(range 98.98-100.42%) of the applied to 90.22% in irradiated soil at 30 days posttreatment and to $89.63 \pm 1.79\%$ (range 87.84-91.42%) in dark control soil at 21 days and were $92.05 \pm 0.64\%$ (91.41-92.69%) at 30 days (Tables 3-4, pp. 32- 33).

Table 6: Phototransformation of [N-phenyl-U-¹⁴C]fenamidone on sandy loam soil expressed as percentage of applied radioactivity (mean \pm s.d., n = 2; except n = 1 for irradiated days 21 and 30 and dark control day 15).

Compound and/or code		Sampling times (days)						
		0	2	5	9	15	21	30
Fenamidone (RPA407213)	irradiated	99.36 \pm 0.74	79.32 \pm 1.21	67.15 \pm 1.55	56.84 \pm 3.76	45.86 \pm 1.37	42.94	31.08
	dark		74.01 \pm 0.73	57.54 \pm 1.99	55.49 \pm 9.19	23.63	16.21 \pm 2.38	17.44 \pm 2.86
RPA405862	irradiated	ND	2.02 \pm 0.07	2.53 \pm 0.23	3.91 \pm 0.73	5.05 \pm 0.63	7.6	7.42
	dark		2.17 \pm 0.09	3.00 \pm 0.91	2.26 \pm 1.96	0.29	0.43 \pm 0.28	1.00 \pm 0.69
RPA410914	irradiated	ND	3.64 \pm 0.54	4.70 \pm 0.06	4.14 \pm 0.32	6.11 \pm 0.85	4.67	5.04
	dark		2.59 \pm 0.36	3.59 \pm 0.09	3.17 \pm 0.26	5.47	5.59 \pm 0.79	6.67 \pm 2.29
RPA406012	irradiated	ND	1.92 \pm 0.03	2.64 \pm 0.28	3.10 \pm 0.12	2.15 \pm 2.16	3.74	2.46
	dark		1.29 \pm 0.23	1.70 \pm 0.08	1.01 \pm 1.01	3.03	0.47 \pm 0.47	1.26 \pm 1.26
Unidentified radioactivity (RT <ca. 43 min.) ¹	irradiated	ND	0.80 \pm 0.10	1.66 \pm 0.52	3.67 \pm 1.09	7.54 \pm 0.73	7.82	7.3
	dark		1.11 \pm 0.07	1.45 \pm 0.55	3.45 \pm 1.71	7.87	7.56 \pm 1.44	7.93 \pm 2.60
Unidentified radioactivity (RT >ca. 43 min.) ²	irradiated	ND	9.07 \pm 0.03	11.46 \pm 0.05	13.17 \pm 0.18	16.09 \pm 0.01	12.27	20.16
	dark		13.47 \pm 0.29	19.19 \pm 0.95	22.50 \pm 0.73	32.41	35.45 \pm 0.17	37.26 \pm 0.23
Total extractable [¹⁴ C]residues	irradiated	99.60 \pm 0.73	96.77 \pm 0.85	91.37 \pm 1.97	86.66 \pm 2.39	86.41 \pm 2.14	82.37	77.03
	dark		94.65 \pm 0.31	88.05 \pm 1.08	89.60 \pm 3.34	76.79	70.59 \pm 0.68	74.82 \pm 1.18
Unextractable [¹⁴ C]residues	irradiated	0.10 \pm 0.01	1.93 \pm 0.08	3.24 \pm 0.39	6.72 \pm 0.36	7.90 \pm 0.22	8.89	9.63
	dark		3.26 \pm 0.29	4.89 \pm 0.38	5.26 \pm 0.18	12.19	14.49 \pm 1.08	13.06 \pm 1.13
CO ₂ and other volatiles ³	irradiated	NA	0.08 \pm 0.01	0.63 \pm 0.35	1.01 \pm 0.0	1.93 \pm 0.03	1.73	3.56
	dark		0.45 \pm 0.04	0.98 \pm 0.25	1.73 \pm 0.32	3.83	4.55 \pm 0.03	4.18 \pm 0.70
Total % recovery:	irradiated	99.70 \pm 0.72	98.78 \pm 0.74	95.23 \pm 2.71	94.39 \pm 2.75	96.24 \pm 1.96	92.98	90.22
	dark		98.37 \pm 0.06	93.92 \pm 0.46	96.59 \pm 3.47	92.81	89.63 \pm 1.79	92.05 \pm 0.64

Data obtained from Tables 3-5, pp. 32-34.; Table 9, p. 37 of the study report. Means reported as calculated by the study author; standard deviations calculated by reviewer.

1 Unidentified radioactivity reported as minor unknowns (RT <ca. 43 min.) in irradiated and dark control soil extracts consisting of up to 9 and 5 compounds, respectively, each comprising <5% of the applied radioactivity (pp. 34, 37).

2 Unidentified radioactivity reported as late eluting peaks (RT >ca. 43 min.) in irradiated and dark control soil extracts consisting of up to 19 and 24 compounds, respectively, each comprising <4% of the applied radioactivity (pp. 35, 38).

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3 Radioactivity recovered in ethylene glycol trapping solutions $\leq 0.01\%$ of the applied (pp. 103, 104, 109, 110, 115, 116, 120, 121, 126, 127, 133, 134).

NA Not analyzed.

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C. TRANSFORMATION OF PARENT COMPOUND: Irradiation did not significantly affect the transformation of [^{14}C]fenamidone when incubated on sandy loam soil; degradation was faster in the dark controls than in the irradiated samples (Figures 4-5, p. 45). In extracts from dark control soil, [^{14}C]fenamidone decreased from a mean $99.36 \pm 0.74\%$ (98.62-100.09%) of the applied at day 0 to $55.49 \pm 9.19\%$ (46.30-64.68%) at 9 days, 23.63% at 15 days and was 13.83-20.31% at 21-30 days (Table 9, p. 37). In extracts from irradiated soil, [^{14}C]fenamidone decreased to $56.84 \pm 3.76\%$ (53.08-60.60%) at 9 days and was 31.08% at 30 days (p. 34 and Attachment 2). The registrant suggested that the slower rate of transformation of [^{14}C]fenamidone on irradiated soil was due to difficulty in maintaining a constant soil moisture content (p. 26).

HALF-LIFE: The half-lives for fenamidone in the irradiated and dark control soil were determined by the reviewer to be 18.7 and 11.0 days, respectively, using linear regression analysis based on first-order kinetics as calculated by Corel Quattro Pro 8 software. DT50 and DT90 values were calculated by the study author using KIM, a nonlinear two-compartment Schering AG kinetic modeling program that determines time for test substance concentration to decline to 50% and 10% of initial concentration. Of the three models tested by the study author, KIM produced the best fit (>-0.98). The models used by the study author are compared in the Reviewer's Comments section of this DER.

Half-lives*

Test system	First order linear			DT50 (days)	DT90 (days)
	Half-life (days)	Regression equation	r^2		
Irradiated	18.7	Linear form $y = mx + b$ as $\ln C = -kt + \ln C_0$; $\ln C_0$ is initial concentration ($b = y$ intercept), $\ln C$ is concentration at time t (y), k is the slope (m), t is time (x) or $kt = \ln C_0 - \ln C$. Half-life ($t_{1/2}$) = $-(\ln 2/k)$.	0.899	12.63	ND
Dark	11		0.925	7.9	40.77

*Half-lives calculated by the reviewer using data obtained from Table 5, p. 34 and Table 9, p. 37 of study report. DT50 values were calculated by the study author using KIM software (pp. 25-26, Table 13, p. 40).

TRANSFORMATION PRODUCTS: No major transformation products were detected in irradiated and dark control soil extracts. Minor transformation products identified in irradiated and dark control soil extracts were RPA405862 detected at maximums of 7.60% (21 days) and 4.22% (9 days) of the applied radioactivity, respectively, RPA410914 detected at maximums of 6.96% (15 days) and 8.96% (30 days), respectively, and RPA406012 detected at maximums of 4.31% (15 days) and 3.03% (15 days), respectively (pp. 34, 37). In addition, up to twenty-nine unidentified [^{14}C]compounds were each detected at $\leq 7.04\%$ of the applied radioactivity (Tables 5-6, pp. 34-35; Tables 9-10, pp. 37-38).

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Table 8: Chemical names for identified transformation products of fenamidone

Applicant's Code Name	CAS Number	Chemical Name(s)	Chemical formula	Molecular weight (g/mol)	Smiles string
RPA405862	153969-11-0	IUPAC: 4-Methyl-4-phenyl-1-phenylaminoimidazolidin-2,5-dione IUPAC: 5-Methyl-5-phenyl-3-phenylaminoimidazolidine-2,4-dione CAS: 2,4-Imidazolidinedione, 5-methyl-5-phenyl-3-(phenylamino)-		281.3	
RPA406012	151022-56-9	IUPAC: 5-Methyl-2-methylthio-3-(4-nitrophenylamino)-5-phenyl-3,5-dihydroimidazol-4-one CAS: 4 <i>H</i> -Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-3-[(4-nitrophenyl)amino]-5-phenyl-			
RPA410914		IUPAC: 5-Methyl-2-methylthio-3-(2-nitrophenylamino)-5-phenyl-3,5-dihydroimidazol-4-one CAS: 4 <i>H</i> -Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-3-(2-nitrophenylamino)-5-phenyl-			

Data obtained from pp. 41, 42, 49-66 of the study report.

NONEXTRACTABLE AND EXTRACTABLE RESIDUES: Extractable [^{14}C]residues decreased from $99.60 \pm 0.73\%$ (98.88-100.33%) of the applied at day 0 to 69.90-76.00% at 21-30 days in dark control soil and 77.03% at 30 days in irradiated soil (pp. 32, 33). Nonextractable [^{14}C]residues increased from $0.10 \pm 0.01\%$ (0.09-0.10%) of the applied at day 0 to 11.93-15.57% at 21-30 days in dark control soil and 9.63% at 30 days in irradiated soil; 1.84-2.55% of the applied was associated with the fulvic acid (in 15- and 30-day dark control and 21- and 30-day irradiated soil samples), 3.20-5.26% with humic acid and 3.03-5.42% with humins (Table 14, p. 40).

VOLATILIZATION: Volatilized radioactivity totaled 3.48-4.58% of the applied for dark control soils at 21-30 days posttreatment and 3.56% for irradiated soils at 30 days. Almost all of the radioactivity was recovered in potassium hydroxide trapping solutions with $\leq 0.01\%$ of the applied recovered in ethylene glycol solutions (pp. 32, 33, 103, 104, 109, 110, 115, 116, 120, 121, 126, 127, 133, 134).

TRANSFORMATION PATHWAY: A transformation pathway for the degradation of [N-phenyl- ^{14}C]fenamidone on soil was not proposed by the registrant because no unique transformation products resulted from the irradiation and no significant transformation products ($>10\%$ of the applied radioactivity) were produced (p. 26). The transformation pathway determined from the

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degradation of [C-phenyl-U-¹⁴C]fenamidone on sandy loam soil (MRID 45385832) was presented (Figure 38, p. 75). In that study, fenamidone degraded to 5-methyl-2-methylthio-5-phenyl-3,5-dihydroimidazol-4-one (RPA408056) via loss of the aniline ring, with further degradation to 5-methyl-5-phenylimidazolidine-2,4-dione (RPA717879) via hydrolysis to release the methylthio group and eventual mineralization to CO₂.

D. SUPPLEMENTARY EXPERIMENT-RESULTS: No supplementary experiments were performed.

III. STUDY DEFICIENCIES: No deficiencies were identified. This study, conducted with [N-phenyl-U-¹⁴C]-labeled fenamidone, can be used to partially satisfy Subdivision N Guideline §161-3 data requirements. This study plus the soil photolysis study conducted with [C-phenyl-U-¹⁴C]-labeled fenamidone (MRID 45385832) fully satisfy Subdivision N Guideline §161-3.

IV. REVIEWER'S COMMENTS

1. In the document *Reduced Risk Rationale for the Use of Fenamidone on Potatoes and Vegetables* (B0003264, no MRID), it is reported that fenamidone is the S-enantiomer compound with none of the R-enantiomer present (p. 16). It is further stated that analysis demonstrated that all of the metabolites of fenamidone that retain the imidazolinone ring are also pure S-enantiomers. No evidence was provided to support this statement.

The registrant's code numbers used in this MRID do not match the code numbers presented in the *Reduced Risk Rationale*. For example, RPA405862 is RPA410193 and RPA408056 is RPA412708. The reason for the different code numbers was not discussed in any document, but the registrant does note in the *Reduced Risk Rationale* that the racemic mixtures were often referenced in the original study reports. To avoid confusion, the chemical codes used in each study report are used throughout this DER.

2. Multiple IUPAC names were found for fenamidone and several of its transformation products. It could not be determined which name was currently preferred. All of the chemical names that were used in the MRIDs in this data package are included in the *Chemical names for identified transformation products* table in this DER and with the attached chemical structures.
3. Half-life/DT₅₀ (50% decline time) values of [C-phenyl-U-¹⁴C]fenamidone on irradiated and dark control soil were determined by the registrant using first order least squares linear regression, Timme-Freshe square-root of first order decay, and KIM two compartment decay kinetic modeling analyses (pp. 40, 91-97). The results of these calculations are compared below:

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Half-life/DT₅₀ values of [N-phenyl-U-¹⁴C]fenamidone on sandy loam soil:

Regression program		Half-life	r ²	DT ₅₀	DT ₉₀
First Order - linear least squares regression using Microsoft Excel 5. Linear form $y = mx + b$ as $\ln C = -kt + \ln C_0$; $\ln C_0$ is initial concentration (b = y intercept), $\ln C$ is concentration at time t (y), k is the slope (m), t is time (x) or $kt = \ln C_0 - \ln C$. Half-life ($t_{1/2}$) = $-(\ln 2/k)$. DT ₉₀ = $-(\ln 10/k)$.	irradiated	19.64 days	0.948	NA ¹	65.25 days
	dark	10.96 days	0.887	NA	36.40 days
Timme-Freshe - Bayer AG program (V.2.0) fits data to 1 st , 1.5 and 2 nd order decay curves. A square-root of the 1 st order decline curve was utilized.	irradiated	11.14 days	0.987	NA	ND ²
	dark	8.23 days	0.945	NA	ND
KIM - Schering AG kinetic modeling program determines time for test substance concentration to decline to 50% and 10% of initial concentration.	irradiated	NA	NA	12.63 days	ND
	dark	NA	NA	7.90 days	40.77 days

¹NA = not applicable.

²ND = not determined.

Data obtained from pp. 40, 91-97 of the study report.

- It appears that the registrant calculated the reported first order half-lives for fenamidone of 19.64 days ($r^2 = 0.9481$) and 10.96 ($r^2 = 0.8872$) days on irradiated and dark control soil, respectively, using mean values of fenamidone (percent of applied radioactivity) detected at each sampling interval (pp. 92, 93). It is preferred that individual replicate values are used for calculations to more accurately reflect the behavior of the compound. However, similar degradation half-lives for fenamidone (18.7 days, $r^2 = 0.927$ and 11.0 days, $r^2 = 0.879$ for irradiated and dark control soil, respectively) were determined by the Dynamac reviewer using [¹⁴C]fenamidone concentrations at all sampling intervals and least squares linear regression analysis assuming degradation followed first order kinetics as calculated by Corel Quattro Pro 8 software (Attachment 2).
- Text and results indicate that each photolysis unit was individually attached to volatiles traps. Figure 3 (p. 44) implies the photolysis units were connected in series to the traps.
- The registrant did not specify how the quantitation methods for the humic acid precipitate and [¹⁴C]residues remaining in the extracted soil (humin).
- The registrant reported that recoveries of radioactivity applied to HPLC columns yielded an overall mean of ca. >105%; however, no supporting data were provided (p. 23).
- The registrant reported that minor unknowns (peaks with HPLC retention times of <ca. 43 minutes) detected in irradiated and dark control soil extracts consisted of up to 9 and 5 compounds, respectively, with each comprising <5% of the applied radioactivity (pp. 34, 37). Similarly, the registrant reported that late eluting peaks (HPLC retention times of >ca. 43 minutes) detected in irradiated and dark control soil extracts consisted of up to 19 and 24

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compounds, respectively, with each comprising <7.5% of the applied radioactivity (pp. 35, 38). This information could not be verified as HPLC chromatograms were only provided for 5-, 15- and 30-day irradiated and dark control soil extracts (pp. 49-66).

9. Soil samples were initially extracted the day of sampling (p. 31). Extracted soil samples and soil extracts were stored at unspecified temperatures until further extraction and/or analysis. Extractions were completed within 34 days of sampling and extracts were stored up to 42 days prior to HPLC analysis.
10. Representative HPLC and TLC chromatograms presented on pp. 48-56, 73, 74 indicated good separation of peaks.
11. The registrant reported that the target application rate was based on the cumulative field maximum application rate of 10 x 150 g a.i./ha which was equivalent a soil surface application of 0.0797 mg a.i./petri dish based on a dish diameter of 2.6 cm (p. 89). The treated soil dishes received 0.0809-0.0833 mg a.i./dish (pp. 99, 100). Based on soil sample weight of 4 g, the treated soils received 20.2-20.8 µg a.i./g soil. In the *Reduced Risk Rationale for the Use of Fenamidone on Potatoes and Vegetables* (B0003264, no MRID), it is stated that the maximum proposed per season application rate is 1.07 lb a.i./A (equivalent to 0.54 mg a.i./kg or 0.60 kg a.i./ha). The application rate was sufficient to allow for identification of all significant degradates.

V. REFERENCES: The following references were cited in the study:

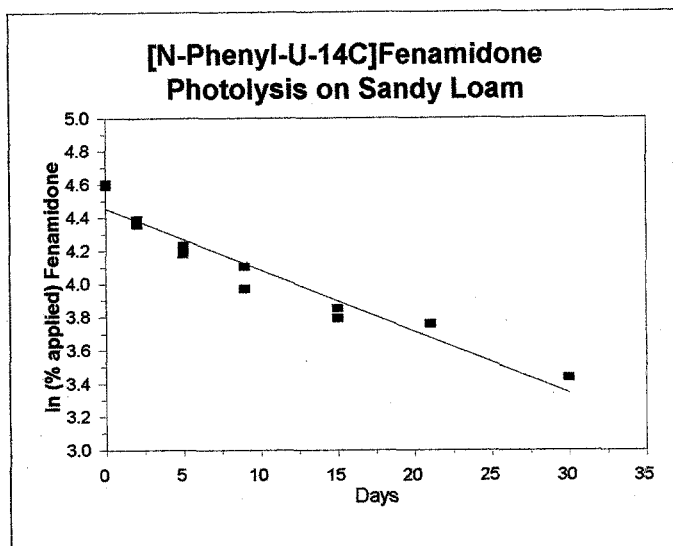
1. Burr, C.M. and A.J. McDonald. 1999. [¹⁴C]-RPA 407213 soil photolysis. Rhône-Poulenc Document 201428.
2. Burr, C.M. and M.B. Simmonds. 1999. [¹⁴C]-RPA 407213 route of degradation. Rhône-Poulenc Document 201609.
3. Walter, H., H. Frehse and Timme. 1993. *Pflanzenschutz-Nachrichten Bayer*, Vol. 46, 3, pp.265-288.

Attachment 1

Quattro Pro Graphs and Spreadsheets

Fenamidone Photolysis on Sandy Loam
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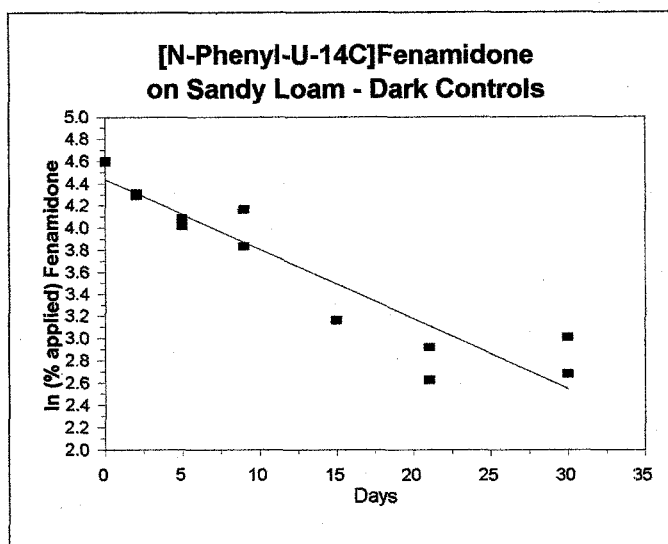
Irradiated		
Half-life of N-Phenyl-U- ¹⁴ C		
Fenamidone		
(HPLC results)		
Day	% AR	Ln(% AR)
0	100.09	4.60607
0	98.62	4.591274
2	80.53	4.38863
2	78.10	4.35799
5	65.59	4.183423
5	68.70	4.229749
9	60.60	4.104295
9	53.08	3.9718
15	47.23	3.855029
15	44.49	3.795264
21	42.94	3.759804
30	31.08	3.436565



Regression Output:

Constant	4.455
Std Err of Y Est	0.101
R Squared	0.927
No. of Observations	12
Degrees of Freedom	10
X Coefficient(s)	-0.03696
Std Err of Coef.	0.003283
half-life	18.7 days

Dark Controls		
Half-life of N-Phenyl-U- ¹⁴ C		
Fenamidone		
(HPLC results)		
Day	% AR	Ln(% AR)
0	100.09	4.60607
0	98.62	4.591274
2	74.74	4.314015
2	73.28	4.294288
5	59.53	4.08648
5	55.55	4.017284
9	64.68	4.169452
9	46.30	3.835142
15	23.63	3.162517
21	13.83	2.62684
21	18.59	2.922624
30	14.58	2.679651
30	20.31	3.011113



Regression Output:

Constant	4.438
Std Err of Y Est	0.265
R Squared	0.879
No. of Observations	13
Degrees of Freedom	11
X Coefficient(s)	-0.06293
Std Err of Coef.	0.007029
half-life	11.0 days

AR = Applied Radioactivity

Linear regression analysis performed using Corel Quattro Pro 8 program.
 Results (% AR) from pp. 34 (irradiated) and 37 (dark controls) of the study report.

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Determination of Standard Deviations for Total Extractable/Unextractable [¹⁴C]Residues, Volatiles and Material Balances.

Day	Extracted [¹⁴ C]			Volatilized [¹⁴ C]			Unextractable [¹⁴ C]			Material Balances		
	% AR	Mean	s.d.	% AR	Mean	s.d.	% AR	Mean	s.d.	% AR	Mean	s.d.
0	100.33			NA			0.09			100.42		
0	98.88	99.61	0.73	NA	0.00	0.00	0.10	0.10	0.01	98.98	99.70	0.72
Irradiated												
2	97.62			0.06			1.85			99.52		
2	95.93	96.78	0.85	0.09	0.08	0.01	2.01	1.93	0.08	98.03	98.78	0.74
5	89.40			0.28			2.85			92.52		
5	93.34	91.37	1.97	0.98	0.63	0.35	3.63	3.24	0.39	97.94	95.23	2.71
9	89.05			1.01			7.08			97.13		
9	84.27	86.66	2.39	1.01	1.01	0.00	6.35	6.72	0.36	91.64	94.39	2.75
15	84.26			1.90			8.12			94.28		
15	88.55	86.41	2.14	1.97	1.94	0.03	7.67	7.90	0.22	98.19	96.24	1.96
21	82.37			1.73			8.89			92.98		
30	77.03			3.56			9.63			90.22		
Dark Controls												
2	94.97			0.49			2.97			98.43		
2	94.34	94.66	0.31	0.41	0.45	0.04	3.55	3.26	0.29	98.30	98.37	0.06
5	89.13			0.73			4.51			94.37		
5	86.97	88.05	1.08	1.22	0.98	0.25	5.27	4.89	0.38	93.46	93.92	0.46
9	92.93			2.05			5.08			100.06		
9	86.26	89.60	3.34	1.42	1.74	0.32	5.44	5.26	0.18	93.12	96.59	3.47
15	76.79			3.83			12.19			92.81		
21	69.90			4.52			13.41			87.84		
21	71.27	70.59	0.68	4.58	4.55	0.03	15.57	14.49	1.08	91.42	89.63	1.79
30	73.64			4.87			14.19			92.69		
30	76.00	74.82	1.18	3.48	4.18	0.70	11.93	13.06	1.13	91.41	92.05	0.64

Results (% AR) from pp. 32 (irrad.) and 33 (dark controls) of the study report.

Means calculated using Corel Quattro Pro 8 program equation @avg(A1..A2).

Standard deviations calculated using Corel Quattro Pro 8 program equation @std(A1..A2).

Replicate Irradiated Dish 8 (21 days) and Dish 7 (30 days) were excluded by the registrant for low material balances.

Replicate Dark Control Dish 14A was excluded by the registrant because the Soxhlet acetonitrile:water extract was lost during processing.

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Determination of Standard Deviations for Parent Fenamidone, RPA408056, RPA717879, RPA409445, Minor Unknowns and Late Peaks.
(HPLC analyses results).

Day	Fenamidone			RPA405862			RPA410914			RPA406012			Minor Unknowns			Late Eluting Peaks		
	% AR	Mean	s.d.	% AR	Mean	s.d.	% AR	Mean	s.d.	% AR	Mean	s.d.	% AR	Mean	s.d.	% AR	Mean	s.d.
0	100.09			ND			ND			ND			ND			ND		
0	98.62	99.36	0.74	ND			ND			ND			ND			ND		
Irradiated																		
2	80.53			2.10			3.10			1.89			0.90			9.10		
2	78.10	79.32	1.21	1.95	2.03	0.07	4.18	3.64	0.54	1.95	1.92	0.03	0.71	0.81	0.10	9.04	9.07	0.03
5	65.59			2.30			4.76			2.92			1.14			11.40		
5	68.70	67.15	1.55	2.77	2.54	0.23	4.64	4.70	0.06	2.36	2.64	0.28	2.19	1.67	0.52	11.51	11.46	0.05
9	60.60			4.64			3.83			2.98			2.58			12.99		
9	53.08	56.84	3.76	3.18	3.91	0.73	4.46	4.15	0.32	3.21	3.10	0.12	4.76	3.67	1.09	13.34	13.17	0.18
15	47.23			4.43			6.96			0.00			6.80			16.10		
15	44.49	45.86	1.37	5.68	5.06	0.63	5.25	6.11	0.85	4.31	2.16	2.16	8.27	7.54	0.73	16.08	16.09	0.01
21	42.94			7.60			4.67			3.74			7.82			12.27		
30	31.08			7.42			5.04			2.46			7.30			20.16		
Dark Controls																		
2	74.74			2.25			2.23			1.52			1.04			13.18		
2	73.28	74.01	0.73	2.08	2.17	0.09	2.95	2.59	0.36	1.06	1.29	0.23	1.19	1.12	0.07	13.77	13.48	0.29
5	59.53			3.91			3.68			1.62			0.90			18.23		
5	55.55	57.54	1.99	2.08	3.00	0.91	3.50	3.59	0.09	1.78	1.70	0.08	2.00	1.45	0.55	20.14	19.19	0.95
9	64.68			0.30			2.92			0.00			1.74			21.77		
9	46.30	55.49	9.19	4.22	2.26	1.96	3.43	3.18	0.26	2.02	1.01	1.01	5.15	3.45	1.71	23.23	22.50	0.73
15	23.63			0.29			5.47			3.03			7.87			32.41		
21	13.83			0.71			6.38			0.00			8.99			35.62		
21	18.59	16.21	2.38	0.15	0.43	0.28	4.79	5.59	0.79	0.94	0.47	0.47	6.12	7.56	1.44	35.28	35.45	0.17
30	14.58			1.69			4.38			2.51			10.53			37.03		
30	20.31	17.45	2.86	0.31	1.00	0.69	8.96	6.67	2.29	0.00	1.26	1.26	5.33	7.93	2.60	37.49	37.26	0.23

Results (% AR) from pp. 34 (irrad.) and 37 (dark controls) of the study report.

Means calculated using Corel Quattro Pro 8 program equation @avg(A1..A2).

Standard deviations calculated using Corel Quattro Pro 8 program equation @std(A1..A2).

Replicate Irradiated Dish 8 (21 days) and Dish 7 (30 days) were excluded by the registrant for low material balances.

Replicate Dark Control Dish 14A was excluded by the registrant because the Soxhlet acetonitrile:water extract was lost during processing.

Attachment 2

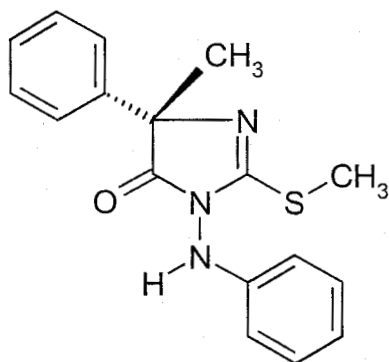
Structures of Parent and Transformation Products

RPA 407213

IUPAC name: (S)-5-Methyl-2-methylthio-5-phenyl-3-phenylamino-3,5-dihydroimidazol-4-one

CAS name: 4*H*-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-, (S)-

CAS #: 161326-34-7

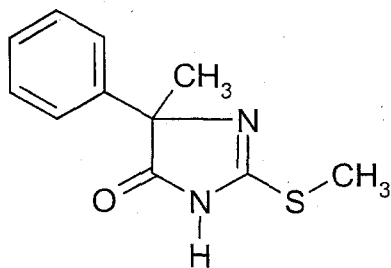


RPA 408056

IUPAC name: 5-Methyl-2-methylthio-5-phenyl-3,5-dihydroimidazol-4-one

CAS name: 4*H*-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-

CAS #: N/A

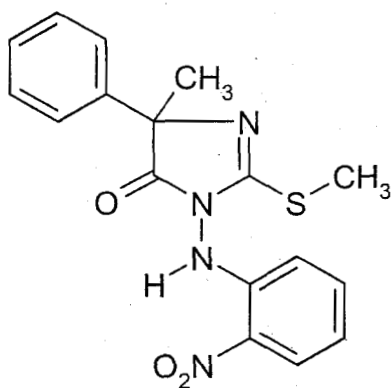


RPA 410914

IUPAC name: 5-Methyl-2-methylthio-3-(2-nitrophenylamino)-5-phenyl-3,5-dihydroimidazol-4-one

CAS name: 4*H*-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-3-(2-nitrophenylamino)-5-phenyl-

CAS #: N/A

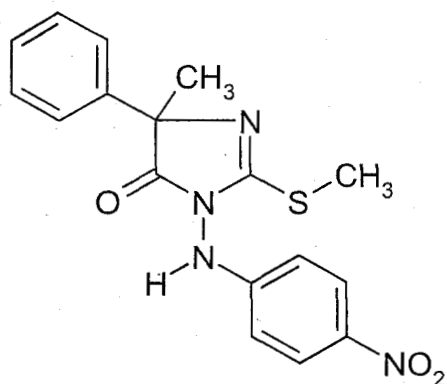


RPA 406012

IUPAC name: 5-Methyl-2-methylthio-3-(4-nitrophenylamino)-5-phenyl-3,5-dihydroimidazol-4-one

CAS name: 4*H*-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-3-[(4-nitrophenyl)amino]-5-phenyl-

CAS #: 151022-56-9



Attachment 3

Transformation Pathway Presented by Registrant
Illustration of Test System
Artificial Light Irradiation Spectrum

Figure 38: Proposed Degradation Pathway

Proposed degradation pathway showing major metabolites observed during previous study [1].

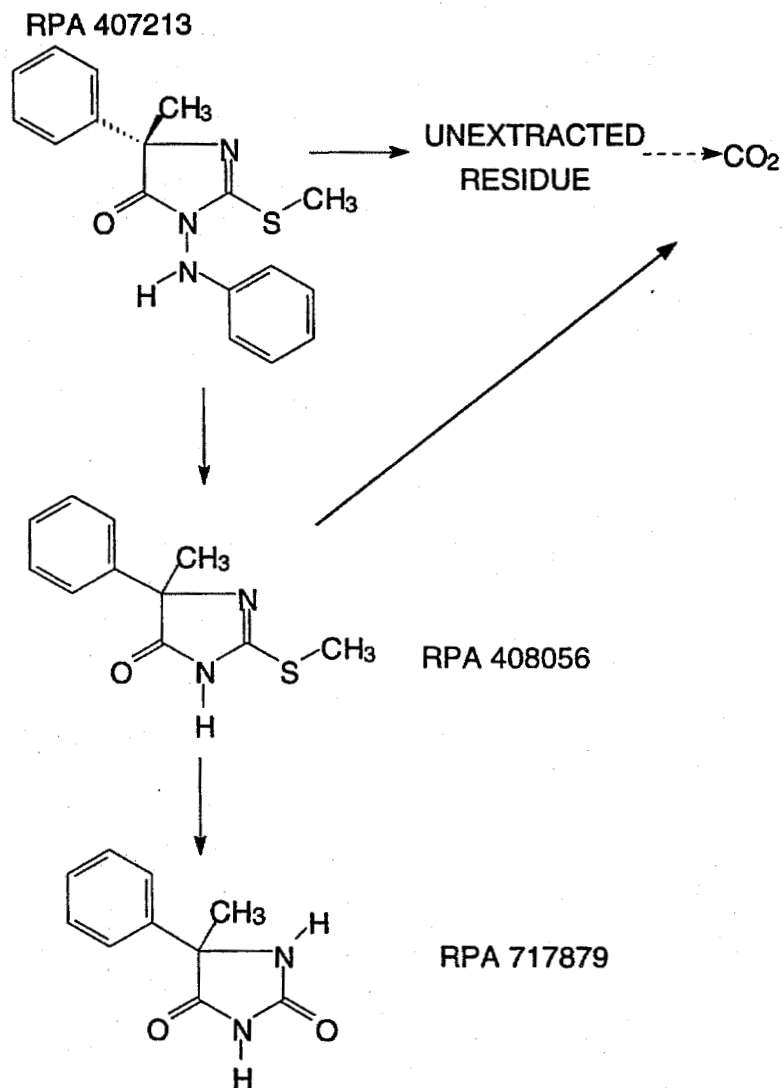
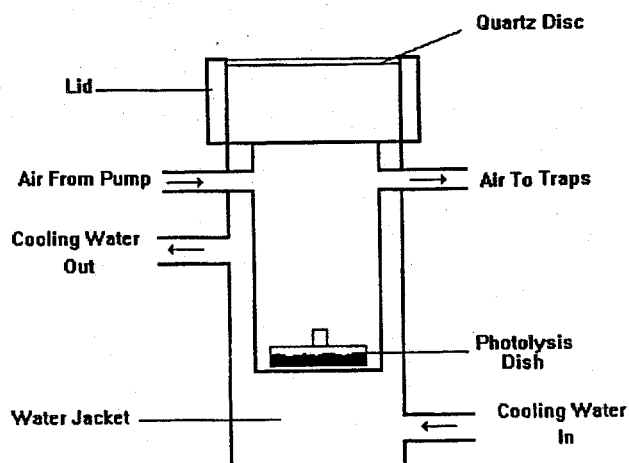
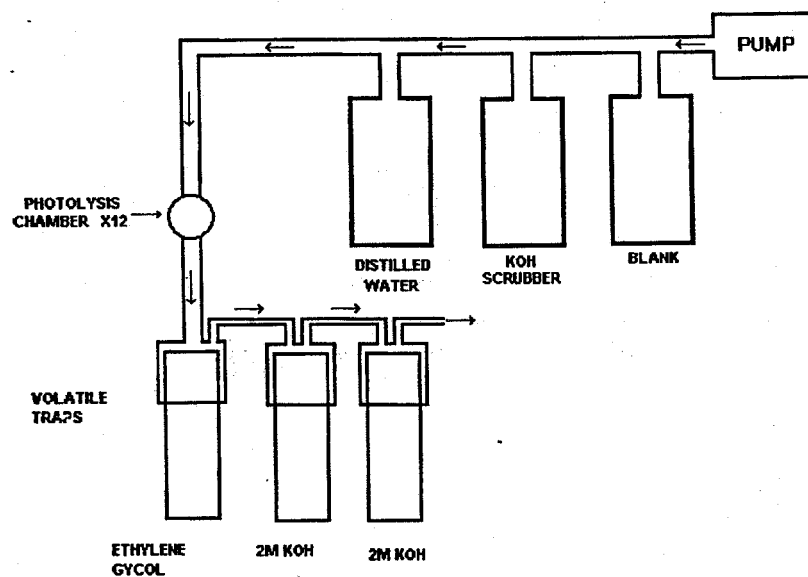


Figure 1: Diagram of Photolysis chamber**Figure 2: Schematic Diagram of Experimental Set-Up**

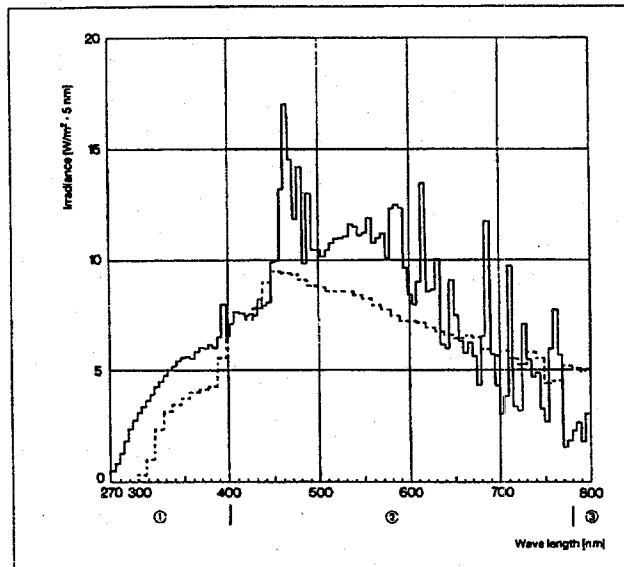
Appendix 3: Light Source

3.1: Spectral Energy Distribution

The Hanau Suntest is fitted with an artificial xenon light source with UV filters which subjects the samples to radiation of wavelength 290 - 800+ nm. The spectral energy distribution of the xenon source in the Hanau Suntest machine is shown below.

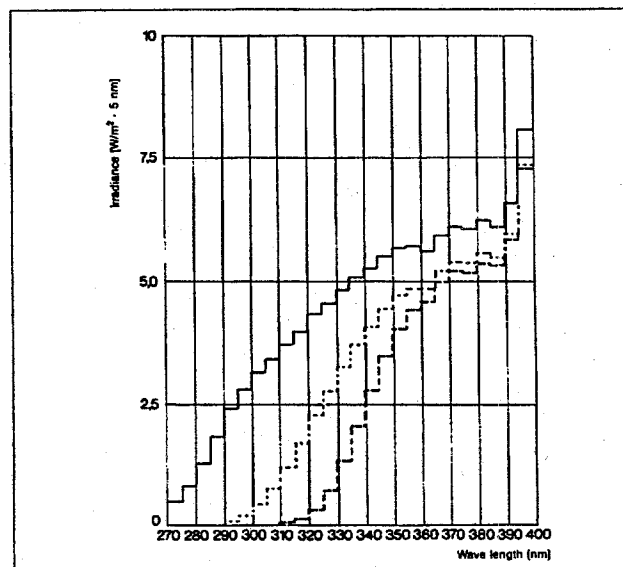
- SUNTEST radiation without additional UV filter
- Global radiation according to daylight D65

- ① UV-Radiation
② visible light
③ IR-Radiation



- without additional filters
- with additional filters of special UV filterglass.
- with additional windowglass filters for test procedures according to simulation of sunlight behind glass.

All figures refer to the maximum irradiance level.



Attachment 1

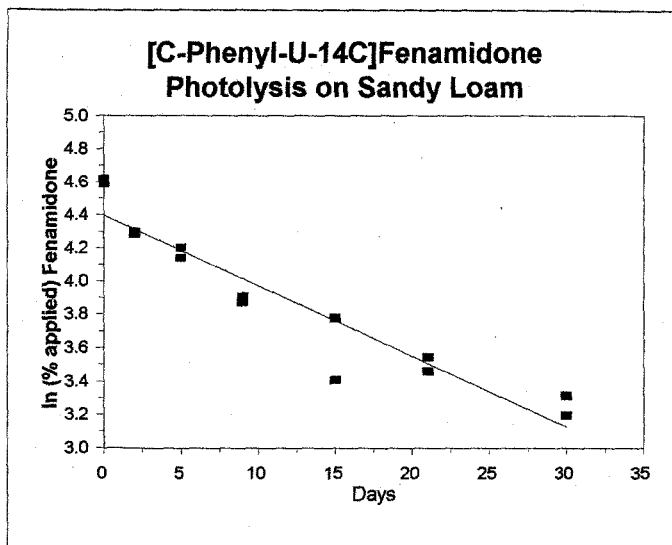
Quattro Pro Graphs and Spreadsheets

Fenamidone Photolysis on Sandy Loam
MRID 45385832

Irradiated		
Half-life of C-Phenyl-U- ¹⁴ C		
Fenamidone (HPLC results)		
Day	% AR	Ln(% AR)
0	98.65	4.591578
0	101.26	4.617691
2	73.64	4.299188
2	72.59	4.284827
5	62.92	4.141864
5	66.88	4.2029
9	48.18	3.874944
9	49.87	3.90942
15	43.85	3.780775
15	30.28	3.410487
21	34.62	3.544432
21	31.85	3.461037
30	27.54	3.315639
30	24.48	3.197856

Regression Output:

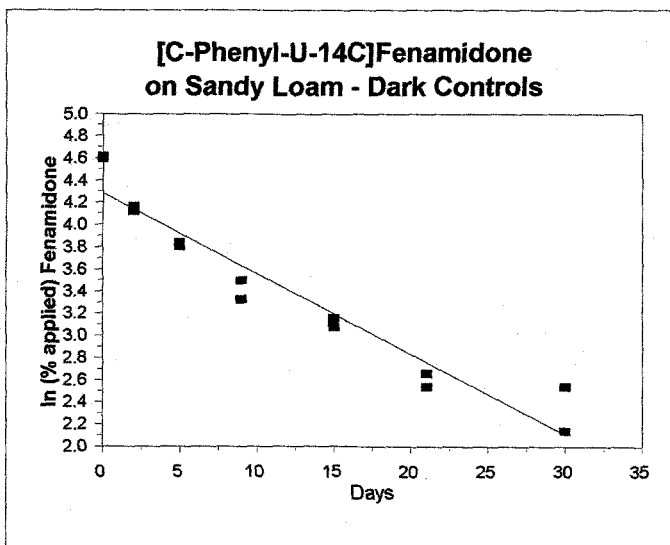
Constant 4.399
 Std Err of Y Est 0.155
 R Squared 0.899
 No. of Observations 14
 Degrees of Freedom 12
 X Coefficient(s) -0.04238
 Std Err of Coef. 0.004102
half-life 16.4 days



Dark Controls		
Half-life of C-Phenyl-U- ¹⁴ C		
Fenamidone (HPLC results)		
Day	% AR	Ln(% AR)
0	98.65	4.591578
0	101.26	4.617691
2	61.63	4.121149
2	64.23	4.16247
5	45.06	3.807995
5	46.70	3.843744
9	27.95	3.330417
9	33.01	3.496811
15	23.55	3.159126
15	21.79	3.081451
21	14.30	2.66026
21	12.72	2.543176
30	12.68	2.540026
30	8.50	2.140066

Regression Output:

Constant 4.286
 Std Err of Y Est 0.222
 R Squared 0.927
 No. of Observations 14
 Degrees of Freedom 12
 X Coefficient(s) -0.07258
 Std Err of Coef. 0.005881
half-life 9.5 days



AR = Applied Radioactivity

Linear regression analysis performed using Corel Quattro Pro 8 program.
 Results (% AR) from pp. 38 (irradiated) and 42 (dark controls) of the study report.

Fenamidone Photolysis on Sandy Loam
MRID 45385832

Determination of Standard Deviations for Total Extractable/Unextractable [¹⁴C]Residues, Volatiles and Material Balances.

Day	Extracted [¹⁴ C]			Volatilized [¹⁴ C]			Unextractable [¹⁴ C]			Material Balances		
	% AR	Mean	s.d.	% AR	Mean	s.d.	% AR	Mean	s.d.	% AR	Mean	s.d.
0	99.82			NA			0.48			100.30		
0	102.49	101.16	1.33	NA	0.00	0.00	0.49	0.49	0.00	102.98	101.64	1.34
Irradiated												
2	92.75			0.15			3.07			95.97		
2	91.94	92.35	0.41	0.18	0.17	0.02	3.45	3.26	0.19	95.57	95.77	0.20
5	89.92			0.39			4.51			94.82		
5	92.30	91.11	1.19	0.30	0.35	0.05	5.29	4.90	0.39	97.90	96.36	1.54
9	88.49			0.90			7.60			96.98		
9	88.76	88.63	0.13	0.73	0.82	0.09	6.61	7.11	0.49	96.10	96.54	0.44
15	86.25			1.10			8.36			95.71		
15	76.61	81.43	4.82	1.21	1.16	0.06	11.47	9.92	1.56	89.29	92.50	3.21
21	80.82			1.65			9.05			91.52		
21	80.10	80.46	0.36	1.63	1.64	0.01	10.60	9.83	0.78	92.33	91.93	0.41
30	82.45			1.90			9.77			94.13		
30	82.21	82.33	0.12	2.59	2.25	0.34	10.53	10.15	0.38	95.33	94.73	0.60
Dark Controls												
2	91.72			0.47			6.48			98.67		
2	91.01	91.37	0.35	0.22	0.35	0.13	5.23	5.86	0.63	96.45	97.56	1.11
5	87.33			0.53			8.47			96.32		
5	86.04	86.69	0.64	0.47	0.50	0.03	7.11	7.79	0.68	93.62	94.97	1.35
9	85.47			1.48			11.08			98.02		
9	86.06	85.77	0.30	1.34	1.41	0.07	10.26	10.67	0.41	97.66	97.84	0.18
15	77.29			3.87			12.61			93.77		
15	76.14	76.72	0.58	3.14	3.51	0.37	12.52	12.57	0.04	91.79	92.78	0.99
21	68.80			7.39			14.29			90.48		
21	65.34	67.07	1.73	5.66	6.53	0.86	14.40	14.35	0.06	85.40	87.94	2.54
30	73.34			6.14			13.51			93.00		
30	70.95	72.15	1.19	10.13	8.14	2.00	16.35	14.93	1.42	97.43	95.22	2.22

Results (% AR) from pp. 36 (irrad.) and 37 (dark controls) of the study report.

Means calculated using Corel Quattro Pro 8 program equation @avg(A1..A2).

Standard deviations calculated using Corel Quattro Pro 8 program equation @std(A1..A2).

Fenamidone Photolysis on Sandy Loam
MRID 45385832

Determination of Standard Deviations for Parent Fenamidone, RPA408056, RPA717879 and RPA409445
(HPLC analyses results).

Day	Fenamidone			RPA408056			RPA717879			RPA409445		
	% AR	Mean	s.d.	% AR	Mean	s.d.	% AR	Mean	s.d.	% AR	Mean	s.d.
0	98.65			0.00			0.00			0.00		
0	101.26	99.96	1.30	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Irradiated												
2	73.64			3.73			1.93			0.00		
2	72.59	73.12	0.52	5.50	4.62	0.88	0.00	0.97	0.97	0.00	0.00	0.00
5	62.92			10.02			0.96			1.13		
5	66.88	64.90	1.98	10.30	10.16	0.14	1.00	0.98	0.02	0.25	0.69	0.44
9	48.18			18.02			3.07			2.04		
9	49.87	49.03	0.84	12.99	15.51	2.52	6.26	4.67	1.59	2.94	2.49	0.45
15	43.85			12.14			8.58			2.36		
15	30.28	37.07	6.79	12.83	12.49	0.35	10.12	9.35	0.77	2.47	2.42	0.06
21	34.62			14.79			9.64			2.03		
21	31.85	33.24	1.38	15.41	15.10	0.31	9.61	9.63	0.02	1.70	1.86	0.17
30	27.54			15.88			12.44			2.28		
30	24.48	26.01	1.53	17.78	16.83	0.95	11.15	11.80	0.64	3.17	2.73	0.45
Dark Controls												
2	61.63			0.00			6.33			0.75		
2	64.23	62.93	1.30	5.76	2.88	2.88	0.00	3.17	3.17	0.58	0.67	0.08
5	45.06			12.72			1.25			1.46		
5	46.70	45.88	0.82	9.59	11.16	1.56	3.45	2.35	1.10	1.18	1.32	0.14
9	27.95			20.41			4.95			2.58		
9	33.01	30.48	2.53	18.59	19.50	0.91	4.25	4.60	0.35	2.18	2.38	0.20
15	23.55			12.24			7.73			2.03		
15	21.79	22.67	0.88	12.05	12.15	0.10	6.77	7.25	0.48	2.26	2.15	0.12
21	14.30			9.03			11.21			0.00		
21	12.72	13.51	0.79	9.02	9.03	0.01	8.75	9.98	1.23	1.35	0.68	0.68
30	12.68			12.97			9.42			1.65		
30	8.50	10.59	2.09	10.52	11.75	1.22	9.68	9.55	0.13	0.91	1.28	0.37

Results (% AR) from pp. 38 (irrad.) and 42 (dark controls) of the study report.

Means calculated using Corel Quattro Pro 8 program equation @avg(A1..A2).

Standard deviations calculated using Corel Quattro Pro 8 program equation @std(A1..A2).

Fenamidone Photolysis on Sandy Loam
MRID 45385832

Determination of Standard Deviations for RPA405862, RPA406012, RPA410914, Minor Unknowns and Late Peaks
(HPLC analyses results).

Day	RPA405862			RPA406012			RPA410914			Minor Unknowns			Late Eluting Peaks		
	% AR	Mean	s.d.	% AR	Mean	s.d.	% AR	Mean	s.d.	% AR	Mean	s.d.	% AR	Mean	s.d.
0	0.00			0.00			0.00			0.00			0.00		
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Irradiated															
2	0.48			0.53			0.00			0.65			6.39		
2	0.70	0.59	0.11	0.52	0.53	0.01	0.00	0.00	0.00	1.05	0.85	0.20	6.35	6.37	0.02
5	1.16			0.55			0.00			2.01			8.97		
5	0.92	1.04	0.12	0.89	0.72	0.17	0.00	0.00	0.00	1.25	1.63	0.38	8.09	8.53	0.44
9	1.44			0.81			0.00			2.75			12.19		
9	2.06	1.75	0.31	1.04	0.93	0.12	0.00	0.00	0.00	3.57	3.16	0.41	10.03	11.11	1.08
15	1.99			0.80			0.00			2.51			13.99		
15	1.56	1.78	0.22	0.58	0.69	0.11	0.00	0.00	0.00	2.66	2.59	0.07	16.12	15.06	1.07
21	1.51			0.40			0.00			3.44			14.39		
21	1.55	1.53	0.02	0.57	0.49	0.09	0.00	0.00	0.00	3.36	3.40	0.04	16.04	15.22	0.82
30	2.34			0.56			0.00			4.63			16.78		
30	1.47	1.91	0.44	0.50	0.53	0.03	0.00	0.00	0.00	5.35	4.99	0.36	18.29	17.54	0.76
Dark Controls															
2	0.73			0.77			0.00			0.78			12.51		
2	0.68	0.71	0.02	0.66	0.72	0.05	0.00	0.00	0.00	0.30	0.54	0.24	10.84	11.68	0.83
5	0.80			0.63			0.00			1.45			19.85		
5	0.83	0.82	0.02	0.74	0.69	0.05	0.00	0.00	0.00	1.29	1.37	0.08	18.39	19.12	0.73
9	0.71			0.68			0.00			2.43			25.75		
9	0.52	0.62	0.10	0.79	0.74	0.05	0.00	0.00	0.00	3.34	2.89	0.46	23.38	24.57	1.19
15	0.79			0.75			0.00			3.23			26.97		
15	1.48	1.14	0.35	0.60	0.68	0.07	0.00	0.00	0.00	4.06	3.65	0.42	27.12	27.05	0.07
21	2.24			0.00			0.00			4.57			27.46		
21	2.55	2.40	0.16	0.33	0.17	0.17	0.45	0.23	0.23	5.51	5.04	0.47	24.66	26.06	1.40
30	1.65			0.22			0.00			6.24			28.52		
30	1.66	1.66	0.01	0.70	0.46	0.24	0.56	0.28	0.28	9.46	7.85	1.61	28.96	28.74	0.22

Results (% AR) from pp. 38 (irrad.) and 42 (dark controls) of the study report.

Means calculated using Corel Quattro Pro 8 program equation @avg(A1..A2).

Standard deviations calculated using Corel Quattro Pro 8 program equation @std(A1..A2).

Attachment 2

Structures of Parent and Transformation Products